K092323

SENORX

5. 510(K) SUMMARY

Date prepared	July 28, 2009
Name	SenoRx, Inc. 3 Morgan Irvine, CA 92618 T. 949.362.4800; F. 949.362.0300
Contact person	Eben Gordon Vice President, RA/QA SenoRx, Inc. T. 949.362.4800; F. 949.362.0300
Device name	Contura Cavity Maintenance Catheter
Common name	Cavity Maintenance Catheter
Classification name	Remote controlled radionuclide source applicator
Classification regulation	21 CFR 892.5700 90 JAQ
Predicate devices	MammoSite Cavity Evaluation Device, K081179 Clearance date: 5/9/2008
Description	The Contura Cavity Maintenance Catheter consists of a dual lumen silicone catheter with an inflatable balloon at its distal end. Two proximal ports are provided with Luer-type connectors for balloon inflation/deflation and for application of intracavitary vacuum. The Contura CMC is available in a spherical, 3.5-5.0 cm diameter balloon size.
Indications for use	The Contura Cavity Maintenance Catheter is temporarily implanted in the lumpectomy cavity as a placeholder until it is exchanged for the Contura MLB Applicator.
Summary of substantial equivalence	Performance testing was conducted to evaluate and characterize the performance of the Contura Cavity Maintenance Catheter. Preclinical testing conducted included dimensional stability of the inflated balloon, burst volume testing, balloon durability in an in vivo setting, and biocompatibility testing. The Contura Cavity Maintenance Catheter performed as intended. The Contura Cavity Maintenance Catheter has the following similarities to the predicate device in that it: has a sub-set of the intended uses; same design; same patient contacting material; same operating principle; and same technological characteristics. The Contura Cavity Maintenance Catheter is substantially equivalent predicate device when used as a placeholder until it is exchanged for a brachytherapy applicator (e.g. Contura MLB Applicator).

AUG 19 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SenoRx, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

AUG 19 2009

Re: K092323
Trade/Device Name: Contura Cavity Maintenance Catheter
Regulation Number: 21 CFR 892.5700
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: JAQ
Dated: July 31, 2009
Received: August 4, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): K092323

Device Name: _____ Contura Cavity Maintenance Catheter _____

Indications for Use:

The Contura Cavity Maintenance Catheter is temporarily implanted in the lumpectomy cavity as a placeholder until it is exchanged for the Contura MLB Applicator.

Prescription Use ___X____ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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